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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/765,287	09/12/97	LOCHT C	960-25

HM12/0316

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EXAMINER	
RYAN, V	
ART UNIT	**PAPER NUMBER**
1641	19

DATE MAILED: 03/16/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/765287	LOCHT et al
Examiner	**Group Art Unit**
V. RYAN	1641

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Peri d for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 12/17/99.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disp sition of Claims

☒ Claim(s) 1-22, 27-31, 34-38 is/are pending in the application.

Of the above claim(s) 36, 38 is/are withdrawn from consideration.

☐ Claim(s)_____ is/are allowed.

☒ Claim(s) 1-22, 27-31, 34, 35, 37 is/are rejected.

☐ Claim(s)_____ is/are objected to.

☐ Claim(s)_____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on_____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on_____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number)_____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received:_____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s)._____

☐ Interview Summary, PTO-413

☒ Notice of References Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other_____

Office Action Summary

DETAILED ACTION

The Examiner acknowledges receipt of the amendment filed December 17, 1999.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

In this application:

Claims 34-38 were added.

Claims 1-22, 27-31, 34-38 are now pending.

Claims 36 and 38 are withdrawn from consideration by the Examiner.

Claims 1-22, 27-31, 34, 35, and 37 are now under examination.

Response to Amendment

Election/Restriction

Newly submitted claims 36 and 38 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 36 and 38 are directed to a vaccine comprised a the recombinant protein and claim 38 is directed to a method of immunizing by administering the protein. In view of the restriction requirement mailed

September 28, 1998 (Paper 12), these claims would have been included in Group II.

Since applicant has received an action on the merits for the originally presented invention (i.e., Group I), this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 36 and 38 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

(1) The objection to the drawings under 37 CFR 1.84 or 1.152 for the reasons stated on PTO 948 is maintained for reasons of record.

(2) The rejection of claims 1-5, 7, 10, 12-21, 27-29 and 30 under 35 U.S.C. 103 as being unpatentable by Menozzi et al is withdrawn.

(3) The rejection of claims 32 and 33 under 35 U.S.C. 112, second paragraph is considered moot in view of the cancellation of the claims. The rejection of claim 7 is withdrawn in view of the amendment.

(5) The rejection of claims 11 and 31 under 35 U.S.C. 103 as being unpatentable by Menozzi et al in view of Relman et al is withdrawn.

The following are new grounds of rejections:

Specification

Claim 31 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 31 refers to claim 34 which is not a previous claim.

Claim Rejections - 35 USC § 112

Claims 16 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 16 and 17 refers to cultures that belong to the species *E. coli*, or belong to a bacterial species other than Bordetella species. Claim 1, however, requires the culture to be Bordetella species. The claims are indefinite because it is not clear what Applicant intends.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-22, 27-31 are rejected under 35 U.S.C. 103 as being obvious by Loosmore et al in view of Menozzi et al.

Loosmore et al (EP 453216) teach bacterial strains transformed with hybrid pertussis genes produced by fusing an ATG codon to a native but autologous pertussis promoter. The reference teaches hybrid genes such as TOXp/FHA and FHAp/TOX and the gene products produced are useful in component vaccines. (See especially Abstract; column 2, lines 24-35, 46-59; column 3, lines 1-16; column 5, lines 33-50; column 6, lines 8-29)

The reference, however, differs in not teaching the binding of FHA with heparin, or the purification of FHA by means of the heparin.

Menozzi et al (FEMS Microbiology Letters 78:59-64, 1991) teach a method of purifying FHA by using heparin. All detectable FHA present in the sample was retained by the heparin media, and no significant degradation of the purified product was observed. (See especially page 62, second column)

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of Loosmore et al to produce a fusion protein comprised of the heparin binding portion of the FHA. One having ordinary skill in the art would have been motivated to do this in so that the protein can be purified with no significant degradation of the FHA component.

Claims 34, 35 and 37 are rejected under 35 U.S.C. 103 as being obvious by Loosmore et al in view of Menozzi et al and further in view of Locht et al.

The teachings of Loosmore et al in view of Menozzi et al were set forth above. The combined teachings include all that is

recited in claim 34 except for mucosal administration of the Bordetella cells expressing the FHA fusion product.

Locht et al (Molecular Microbiology 9(4):653-660, 1993) teaches that immune responses against FHA appear to protect against colonization. Intranasal immunization of mice with purified FHA resulted in the production of anti-FHA IgG in both sera and nasal secretions, and of anti-FHA IgA only in bronchoalveolar lavage fluids. Furthermore, Locht et al suggest that the presentation of antigens, such as the FHA, to the mucosal immune system may be important for efficacious and long-lasting immunity. (See especially page 658, second column)

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further apply the modified composition of Loosmore et al to the mucosal immune system. One having ordinary skill in the art would have been motivated to do this to achieve efficacious and long-lasting immunity, as per the teachings of Locht et al.

The Group and/or Art Unit location of your application in the Patent and Trademark Office may have changed. To aid in correlating any papers for this application, all further

correspondence regarding this application should be directed to Group Art Unit 1641.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to V. Ryan whose telephone number is (703)305-6558.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-0196.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027.

Papers related to this application may be submitted to the Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax number for Art Unit 1641 is (703)308-4242.

V. Ryan
Patent Examiner/Art Unit 1641
March 2000
Ryan/vr

James C. Housel 3/13/00
JAMES C. HOUSEL
SUPERVISORY PATENT EXAMINER